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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/544,897	02/02/2006	Ralf Dunkel	CS-8582/LeA 36,354	6478
34469 BAYER CROI	7590 07/08/200 PSCIENCE LP	EXAM	EXAMINER	
Patent Departn	nent	HAVLIN, ROBERT H		
	ANDER DRIVE RIANGLE PARK, NC	ART UNIT	PAPER NUMBER	
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			07/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/544,897 DUNKEL ET AL. Office Action Summary Examiner Art Unit ROBERT HAVLIN 1626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 14 May 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 19-22.28 and 33 is/are pending in the application. 4a) Of the above claim(s) 33 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 19-22 and 28 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

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DETAILED ACTION

RCE: A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/09 has been entered.

Status of the claims: Claims 19-22, 28, and 33 are currently pending.

Priority: This application is a 371of PCT/EP04/01053, filed on February 5, 2004 and claims benefit under 35 U.S.C. 119(a)-(d) to foreign applications Germany 10306244.0, filed February 14, 2003 and Germany 10321270.1, filed May 13, 2003.

Restriction: Applicant previously elected group I (claims 19-26, 28, 31-33, drawn to compounds of formulae I, IV, VI, and VIII).

Applicant previously elected the species # 39 (of the amended specification) of

the formula

(where Z=1-methylbutyl).

In accordance with the election of species, no generic claim was allowable, therefore the scope of the claims were restricted to the elected species only. Thus subject matter not reading on the elected species is held withdrawn until a generic claim is found allowable. Accordingly, claim 33, which does not read on the elected species is held withdrawn. See MPEP \$ 803.02.

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RESPONSE TO APPLICANT REMARKS

Claim Rejections - 35 USC § 103

 Claims 19-22, 28, and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al. (Han'guk Nonghwa Hakhoechi (2001), 44(3), p. 191-196).

Applicant argues (1) that structural features distinguish the claims from the prior art and (2) the data previously presented and considered fully support the patentability of the claims.

(1) Regarding the structural differences, the examiner previously pointed out in the prior office actions. Hahn teaches "R" alkyl homologues of the structure



each of which is measured for bacterialcidal activity. Since a significant number of the compounds known to be alkyl homologues tested by Hahn showed activity those of ordinary skill in the art would be substantially informed that other alkyl homologues of the R alkyl group would also continue to show the demonstrated activity. Therefore, the addition of two methylene groups onto the Hahn's compound #53 is a clear homologue and remains obvious to one of ordinary skill in the art.

(2) Regarding the three declarations (WN-D1, WN-D2, and V), the examiner has fully considered them and found them not persuasive as to an unexpected result because of the inconsistent results of compound #53 being less effective at a higher concentration and for a lack of error analysis clearly showing the confidence intervals of the measurements. The examiner is willing to entertain withdrawing the rejection if

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confidence intervals for the measurements are presented that are consistent with an unexpected result. However, the data a presented remains unpersuasive.

The rejection is maintained.

NEW CLAIM REJECTIONS

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 19-22, and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/588491. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are for overlapping subject matter. Specifically, the '491 claims are for a genus of compounds of the following formula:

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$$A \xrightarrow{\bigcap_{R^1} \prod_{L^1_{Q} \subset L^2_{R}}} (I)$$

where the variables are defined in a similar manner as the instant claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - Resolving the level of ordinary skill in the pertinent art.
 - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 19-22, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eicken et al. (US 5,589,493) in view of Thomber (Chem. Soc. Rev., 1979, v. 8, p. 563-580).
 - Determining the scope and contents of the prior art.

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Eicken et al. teaches compounds suitable as fungicides suitable for use on plants. The reference teaches in col. 17 the following fungicidal compounds (Table 8):

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Compounds of the formula V when A is A ₂ 2.3 2.5 3.5 3.5 2.5 3.					TABLE 8-continued			
TABLE 8 E.35 2 a Pentylony E.35 a					Compounds of the formula V where A is A ₂			
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Specifically, compounds 8.8 and 8.69 are of interest where n=2 and 1 and R7 is secpentyl.

Thornber teaches methodologies routinely employed by chemists to optimize and discover new compounds based on structural similarity. Thornber specifically teaches

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how "classical" isosteric replacement includes modifying a methyl group to a halogen. See page 564.

Ascertaining the differences between the prior art and the claims at issue.
 The difference between Eicken compounds and the claims is a methyl group versus a halogen on the oxathiin ring at the 2-position.

3. Resolving the level of ordinary skill in the pertinent art.

One of ordinary skill in the art of fungicide development would be well versed in the teachings of references such as Thornber. One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering the substituents on drug molecules and screen them for activity on a large scale to improve potency or discover new compounds with desirable properties.

 Considering objective evidence present in the application indicating obviousness or nonobviousness.

One of ordinary skill in the art would be motivated to optimize or modify the compound identified by Eicken and perform isosteric replacement as taught by Thomber.

In Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd., 87 USPQ2d 1452, 1454 (Fed. Cir. 2008), the Federal Circuit clarified the proof of obviousness in structural similarity situations such as this:

Where, as here, the patent at issue claims a chemical compound, the analysis of the third Graham factor (the differences between the claimed invention and the prior art) often turns on the structural similarities and differences between the claimed compound and the prior art compounds. See Eli Lilly & Co. v. Zenith

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(noting that, for a chemical compound, a prima facie case of obviousness requires "structural similarity between claimed and prior art subject matter ... where the prior art gives reason or motivation to make the claimed compositions" (quoting In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc))). Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. See Takeda Chem. Indus. v. Alphapharm Ptv., Ltd., 492 F.3d 1350, 1356 [83 USPQ2d 1169] (Fed. Cir. 2007). In keeping with the flexible nature of the obviousness inquiry. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 [82 USPQ2d 1385] (2007), the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. See Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1301 [84] USPQ2d 1198I (Fed. Cir. 2007). Rather "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship ... to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." Id. (quoting Dillon, 919 F.2d at 692). In addition, the prior art compound shows a very close structural relationship to

Goldline Pharms., Inc., 471 F.3d 1369, 1377 [81 USPQ2d 1324] (Fed. Cir. 2006)

the claimed compound that one of ordinary skill in the art would know conclude they have similar properties based on the knowledge and experience of those of ordinary skill in the art and the teachings of the prior art as a whole.

Therefore, the claims are rejected.

Conclusion

The claims are not in condition for allowance.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/ Examiner, Art Unit 1626